Remarks

Reconsideration of the above-identified application is respectfully requested.

Claim 17 remains in the application and it has been amended to show the proper pH range for treatment of the protein source with pepsin derived from fish, specifically Atlantic cod, for the time necessary to effect hydrolysis of the protein source.

In the Advisory Action dated July 25, 2003, the rejection of Claim 17 under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) over the prior art was maintained. In the response to the Office Action dated April 9, 2003, Applicant had amended Claim 17 to show the intended use of the composition in the preamble of the claim. The Examiner stated in the Advisory Action that the intended use of the composition is usually given little weight in distinguishing over the prior art.

The Fujimaki et al. reference shows the preparation of a low phenylalanine plastein and not a bioactive peptide composition that enhances the growth of animals and fish. In the Fujimaki et al. reference in Column 3, there is described an enzymatic hydrolysis reaction wherein the hydrolysis is carried out by dissolving or suspending raw protein material into water with a suitable enzyme having an endopeptidase activity. The choice of enzymes may be pepsin or chymotripsin. At line 25, it states, moreover, "it is advantageous to lower the active range of the pepsin as low as below pH 2 in order to prevent the unfavorable putrefacation of the substrate during the incubation." The pepsin choice appears to be "Difco pepsin" at column 3, line 34. The currently claimed invention is diverse from the Fujimaki reference. Claim 17 requires a pH range of 2-6. In the enzymatic hydrolysis of the protein source in the present invention, pepsin enzyme is used and specifically pepsin enzyme from a fish source, and more specifically pepsin from Atlantic cod. The specific pepsin used to treat the protein in the present invention creates a composition "that enhances the growth of animals and fish" as currently described in the preamble of Claim 17.

In the reference, additional experiments were performed to determine the hydrolysis under various pH conditions in considering the reaction of an enzyme at different pH readings. The enzyme used was Pronase, which is a mixture of at least six different proteases including exopeptidases, which are not pepsin enzymes.

The application that led to the <u>Fujimaki et al.</u> reference was filed in the United States on January 16, 1976. Applicants' can find no reference concerning the use of pepsin derived from fish at the time of the filing the application. Indeed, Applicants have searched a website catalog of a major supplier of chemical and biological products and found six references to pepsin derived from hogs. Applicants have found no reference for pepsin derived from fish available

from the chemical and biological supply company as of October, 2003, and none from Difco. It is unlikely that pepsin derived from fish, or specifically derived from Atlantic cod, would have been available in 1976 for use in the method described in the Fujimaki et al. reference. There is no indication in the Fujimaki et al. reference that pepsin derived from fish or more specifically from Atlantic cod was used in the enzymatic hydrolysis shown therein. Most commercially available pepsin is derived from hogs. The pepsin from cod and the pepsin from hog are two totally different enzymes. The enzymes are completely diverse regarding important qualities such as: pH-optimum, isoelectric point, temperature optimum, stability, amino acid, and substrate specificity. In general, warm-blooded animals and fish, which are adapted to cold environments, have totally different pepsins. The common name "pepsin" relates to the fact that the enzymes are isolated from the "peptic organ/stomach." It is well known in the art that the catalytic site for cod pepsin differs from the catalytic site for mammalian pepsins. Knowing this, it is highly unlikely that one skilled in the art would follow the teachings of the Fujimaki et al. reference to render obvious the present invention, and in no way can the Fujimaki et al. reference anticipate Claim 17 of the present invention if an entirely different pepsin was used in preparing low phenyalanine plastein, which is totally diverse from the composition claimed by Applicants. Clearly, the Fujimaki et al. reference does not anticipate Claim 17.

With reference to <u>Yamashita et al</u>. reference, the same type of reasoning applies. The reference was published in 1976 and states in the Results and Discussion section, in the second paragraph, that pepsin was added to a fish protein concentrate and soy protein isolate in a dilute acidic solution. The pepsin was obtained from Difco, and as stated above, Difco no longer manufactures pepsin according to their website. Clearly one skilled in the art would not follow the teachings of the <u>Yamashita et al</u>. reference to produce Applicants claimed invention nor would the disclosure in the <u>Yamashita et al</u>. reference anticipate Claim 17.

As stated above, it can be reasoned that pepsins were obtained from hogs at the time of the publication of the <u>Yamashita et al.</u> reference, not from fish, and not specifically from Atlantic cod. Further, Pronase, which is also used in this reference, is not a pepsin and cannot be anticipatory of the use of pepsin in describing the composition of Claim 17. Clearly, the rejections under 35 U.S.C. § 102 and 103 should be withdrawn.

Applicants request an early Notice of Allowance of the above-identified application.

Respectfully submitted,

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W. Dennis Drehkoff Attorney for Applicant

Ladas & Parry

224 S. Michigan, Ste. 1200

Chicago, IL 60604 312-427-1300 Reg. No. 27193